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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,093

04/11/2005

Udi Damari

26479U

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20529

7590

02/18/2009

THE NATH LAW GROUP

112 South West Street

Alexandria, VA 22314

EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

PAPER NUMBER

1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,093	<b>Applicant(s)</b> DAMARI ET AL.	
	<b>Examiner</b> KARLHEINZ R. SKOWRONEK	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 75-91 is/are pending in the application.
- 4a) Of the above claim(s) 89 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75-88 and 91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 November 2008 has been entered.

### ***Claim Status***

Claims 75-91 are pending.

Claims 1-74 are cancelled.

Claims 89-90 are withdrawn as being directed to a non-elected invention the election having been made on 24 August 2007 without traverse.

Claims 75-88 and 91 have been examined.

Claims 75-88 and 91 are rejected.

### ***Priority***

This application is the National stage filing of PCT/IL03/00544 filed on 29 June 2003 which claims the benefit of U.S. Provisional Application No. 60/391,575 filed on 27 June 2002 and U.S. provisional Application No. 60/417,460 filed on 10 October 2002.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 75-88 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianaroli et al. (Human Reproduction, Vol. 15 No. 10, p 2241-2246, 2000), in view of Whisler et al. (Clinical Chemistry, Vol. 36, No9, p. 1587-1588, 1990) in view of England (U.S. Pat 5,510,604) and in view of Krupa (U.S. PGPUB 2002/0093189).

The claims are directed to a method of controlling the processing of components involved in an *in vitro* fertilization (IVF) in which a matching set of two or more components are defined; each of the components is assigned a unique machine-readable identification mark; providing on each component the identification mark; generating photographic images of the machine-readable identification mark; reading the identification marks of two components simultaneously to verify that the component belongs to the matching set. In some embodiments, the components that are marked are consists of holders, physician, embryos, oocytes, spermatozoa. In some embodiments, the matching set includes an embryo and a recipient. In some embodiments, the identification mark assigned to components is different. In some embodiments, the matching set includes a sperm and an oocyte. In some embodiments, a matching set corresponds to a biological entity and a holder. In some embodiments, an entity is within a holder and the holder is labeled. In some embodiments, the identification marks assigned to the components are the same. In some embodiments, the patient and their records are matched through the assignment of an identification mark. In some embodiments, the barcode is readable by scanning. In some embodiments, the identification mark is a barcode. In some embodiments, the identification mark is an image readable mark. In some embodiments, a label having the identification mark is affixed to a holder.

Gianaroli et al. shows a method for controlling the processing of components used in *in vitro* fertilization. Gianaroli et al. shows that a matching set of two or more components is defined and that the components are assigned a unique identification (p.

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2243, col. 1, sect 4). Gianaroli et al. shows that unique identification mark is used to verify the components belong to the correct patients (2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment the components that are marked are consists of holders, physician, embryos, oocytes, and spermatozoa (p. 2243, col. 1 -2244, col. 1). Gianaroli et al. shows in an embodiment, that the identification mark assigned to components is different (p. 2244, col. 1, sect. 7.2). Gianaroli et al. shows in an embodiment that the matched set is an embryo and a recipient (p. 2245, col. 1-2). Gianaroli et al. shows in an embodiment that the matching set includes a sperm and an oocyte (p. 2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment in which an entity is within a holder and the holder is labeled, reading on the embodiments of at least an entity is within a holder, where the holder is labeled with identification mark and a matching set corresponding to a biological entity and a holder (p. 2245, col.2, sect. 12.6). Gianaroli et al. shows that the identification marks assigned to the components are the same (2243, col. 1, sect. 4). Gianaroli et al. shows an embodiment in which the patient and their records are matched through the assignment of an identification mark (p. 2241, col. 2 sect 2).

Gianaroli et al. does not show that the unique identification is machine-readable.

Whisler et al. shows use of machine-readable identification marks and shows the identification marks are used to control the automatic processing of medical specimens. Whisler et al. shows that the machine-readable identification mark is a barcode (p. 1588, col. 1). Whisler et al. shows that bar-coding is highly accurate and machine-readable information is more reliable than manually entered data (p. 1588, col. 2). Whisler et al. shows that the barcode is readable by scanning (p. 1588, col. 2). Whisler

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et al. shows the identification mark is an image readable mark (p. 1588, figure 1).

Whisler et al. shows that a label having the barcode is affixed to a specimen tube label (p. 1588, col. 2).

England shows that barcodes can be read by imaging. England shows that barcodes are photographically imaged by scanning to "lift" the image via a video camera (col. 3, line 50-54). England shows that the scanned image is stored (col. 5 line 17-20). England shows the process of scanning and storage of barcode images has the advantage providing the capability of being archived and used in auditing (col. 1, line 61-62).

Krupa shows that barcodes can be read simultaneously. Krupa shows that a matched pair of components with associated barcodes or machine-readable identification marks is simultaneously read by a barcode reader [0042]. Krupa shows that by reading the barcodes simultaneously, it is possible to verify the correspondence of the data encoded by the barcode to the components [0042]. Krupa shows if the data of the barcode does not match the components, a correction is made before the process is continued [0049]. Krupa shows the advantage verifying the correspondence of bar-coded data to the components is that it is useful for quality control and inventory [0015].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify procedures of processing IVF components of Gianaroli et al. with the use of barcodes in medical specimen processing of Whisler et al. because Whisler et al. shows that bar-coding is highly accurate and machine-readable

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information is more reliable than manually entered data. It would have been further obvious to modify the method of Gianaroli et al. in view of Whisler for computer tracking of In Vitro Fertilization (IVF) procedures and components using barcodes with the imaging of barcodes of England because England shows barcode imaging has the advantage of providing the capability of being archived and used in auditing. It would have been further obvious to modify the method of Gianaroli et al. in view of Whisler for computer tracking of IVF procedures and components using barcodes by imaging more than one component simultaneously as Krupa because Krupa shows that by imaging more than one barcode simultaneously provides the advantage of allowing one to verify the correspondence of the bar-coded data with the components which is useful to the auditing process of quality control and inventory. The combinations of Whisler et al. with England and Krupa flow logically from each other. Where Whisler et al. shows the benefits to record keeping and sample tracking in the medical laboratory setting, England and Krupa show that the barcode imaging and simultaneous reading of more than one barcode in the medical setting provide the ability to maintain correspondence between paired components by auditing and archiving to maintain quality control and inventory. It would have been further obvious to modify the method for good practice of IVF of Gianaroli et al. with the automation and bar-coding of Whisler et al., the barcode photographic imaging of England and the simultaneous reading of barcodes of Krupa because a method of enhancing the processing of IVF components through the application of automation and bar-coding was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in the medical



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laboratory and pharmacy. One of ordinary skill in the art would have been capable of applying this known method of enhancement to the processing of IVF components through the application of automation and bar-coding in the prior art and the results would have been predictable to one of ordinary skill in the art.

### ***Response to Arguments***

Applicant's arguments filed 13 November 2008 have been fully considered but they are not persuasive. Applicant argues that the combination of Gianaroli et al. in view of Whisler et al. fails to teach or suggest the photographic imaging of barcodes and reading more than one barcode simultaneously. The argument is not persuasive because the rejection modified shows the elements of photographic imaging of barcodes and reading more than one barcode simultaneously. Specifically, England shows that barcodes can be photographically imaged. Whereas, Krupa shows that multiple barcodes can be read simultaneously. The combinations of Whisler et al. with England and Krupa flow logically from each other. Where Whisler et al. shows the benefits to record keeping and sample tracking in the medical laboratory setting, England and Krupa show that the barcode imaging and simultaneous reading of more than one barcode in the medical setting provide the ability to maintain correspondence between paired components by auditing and archiving to maintain quality control and inventory. The rejection is maintained.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/  
Examiner, Art Unit 1631

18 February 2009